Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

Notice

10 OCT 2022

File No. 29/Misc./03/2020-DC (140) Part-5 (a) **Date:**

Subject: Classification of Medical Device pertaining to Dental under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, sale and distribution, clinical investigation, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which is already implemented from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the medical devices, based on the intended use, risk associated with the device and other parameters specified in the First Schedule of the Medical Devices Rules-2017

Updated list of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic in nature and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

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Classification of Medical Devices Pertaining to Dental

S. No.	Medical Device Name	Intended Use	Risk Class
1	Dental impression material	This material is primarily used to take an oral impression.	A
2	Dental collar/crown scissors	Scissors use to cut delicate tissue to removing sutures to performing precision procedures.	A
3	Dental excavator, reusable	It is a device intended to cutting, clean out and shape a carious cavity before filling it.	A
4	Dental excavator, single-use	It is a single use device intended to cutting, clean out and shape a carious cavity before filling it.	A
5	Dappen dish, reusable	It is a small bowls used to mix and hold dental materials. These dishes can be disposable or reusable	A
6	Dappen dish, single-use	A small, shallow concave vessel used to knead and hold dental materials.	A
7	Dental examination kit	Intended as a kits for dental examination.	A
8	Dental crown, polymer	A device made entirely of polymer-based material with or without fibre reinforcement, and created for a specific patient, that functions as an artificial covering to replace the major part, or the whole part, of the clinical crown of a tooth.	B
9	Dental crown/bridge resin, temporary	A material used to manufacture crowns and bridges.	B
10	Dental crown/bridge, temporary	Intended to make a temporary crown or bridge prosthesis for use until a permanent restoration is fabricated.	B
11	Dental material mixing surface, reusable	A dental instrument slab or tray used as a surface to mix dental materials.	A
12	Dental material mixing surface, single-use	It has pad or tray used to knead or mix dental material (impression material, cement, etc).	A
13	Dental spatula, reusable	A dental instrument used to mix dental materials. Some are equipped with an injection function.	A
14	Dental spatula, single-use	A spatula-shaped device used to knead or mix dental material (impression material, cement, etc).	A
15	Dental crown, metal/ceramic	A device made of a combination of metal and tooth-coloured ceramic, that functions as an artificial covering to replace the major part, or the whole part, of the clinical crown of a tooth.	B
16	Dental crown, metal/polymer	A device made of metal, veneered with a polymer-based, tooth-coloured material, and created for a specific patient, that functions as an artificial covering to replace the major part, or the whole part, of the clinical crown of a tooth.	B

17	Dental impression material kit, reusable	Devices and materials used to take the impression.	A
18	Dental impression material kit, single-use	A collection of non-sterile devices designed to obtain a negative imprint of the teeth. The kit typically includes dental impression materials and a dental impression tray(s); This is a single-use device.	A
19	Dental impression material mixer	An electric device used to mix impression materials immediately before use at the chair side.	A
20	Dental impression material syringe	This dental injection syringe is used to inject the impression material onto the impression tray.	A
21	Dental impression tray material	A material intended to be used to create a custom impression tray intended for filling with dental impression materials; it is not intended for the fabrication of a patient-worn dental appliance. The material is used in cases in which a preformed impression tray is not suitable.	A
22	Dental impression tray, reusable	A impression tray is a metal or plastic device intended to hold impression material, to make an impression of a patient's teeth to reproduce the structure of a patient's teeth.	A
23	Dental polishing brush	A rotary dental brush intended for cleaning and polishing by a dental hygienist or a dentist.	A
24	Dental bone particle collector	A device used to collect bone debris generated by drilling, etc. during oral surgery.	B
25	Dental bone matrix implant, animal-derived	A sterile bio absorbable device made primarily of animal-derived bone or dentin matrix (e.g., bovine, porcine) implanted into the body to provide osteoconductive bone-tissue scaffolds to replace maxillofacial and/or mandibular bone lost through trauma or dental surgery. It is used to fill bone cavities and defects and contains pores that promote the ingrowth of endogenous bone for skeletal reconstruction and/or augmentation.	C
26	Dental suction system	It evacuate solids, liquids, aerosols and gases from the oral cavity and immediate surrounding area for the purpose of improving operating effectiveness and efficiency during oral treatment procedures and limiting the contamination of the immediate environment.	B
27	Dental suction system cannula, reusable	A tubal dental device to be connected to a non-active aspiration device (usually, a dentistry dedicated device). Used to eliminate water and cutting debris that have accumulated in the oral cavity. This device is reusable after sterilization.	A
28	Dental suction system cannula, single-use	A tubal dental device to be connected to a non-active aspiration device (usually, a dentistry dedicated device). Used to eliminate water and cutting debris that have accumulated in the oral cavity.	A
29	Carboxymethylcellulose sodium denture adhesive	An adhesive compound composed of carboxymethylcellulose sodium (usually 40 to 100%) used to stabilize a removable prosthesis in the mouth, particularly a denture, by adhering the prosthesis to the oral mucosa. The compound is typically applied to the base of a denture before it is inserted in the mouth.	B

30	Carboxymethylcellulose sodium/polymer denture adhesive, zinc-free	An adhesive compound intended to be used to stabilize a removable prosthesis in the mouth, particularly a denture, by adhering the prosthesis to the oral mucosa. The compound is typically applied to the base of a denture before it is inserted in the mouth.	B
31	Dental amalgam	A dental restorative material used primarily to fill tooth cavities, prepared by mixing liquid mercury (Hg) with an alloy of fine particles, composed mainly of silver (Ag), tin (Sn) and copper (Cu).	B
32	Dental suction system fluid-separation unit	A separator used in the oral cavity. Used for the separation of fluids (saliva, blood) from gases to avoid liquids from entering the suction pump (i.e., dry suction).	A
33	Dental suction system pump	An electrically-powered dental suction pump used as the suction source of a dental suction system, dental treatment unit, etc.	B
34	Temporary mandibular condyle prosthesis	A sterile implantable device intended for the temporary reconstruction of the mandibular condyle of the temporomandibular joint (TMJ) typically in a patient undergoing ablative surgery requiring the removal of the mandibular condyle.	C
35	Temporomandibular joint disc	A sterile interpositional implant or interarticular disc, intended to permanently interface between the natural mandibular condyle and natural glenoid fossa (mandibular fossa) in the temporomandibular joint (TMJ).	C
36	Bar dental precision attachment	It connect removable partial dentures to fixed bridgework under a male/female locking mechanism.	A
37	Dental suction system disinfection control unit	An electrically-powered device intended to control the regular (typically daily) automated/semi-automated disinfection of a dental suction system tubing line.	B
38	Transgingival implant	A sterile device intended to be surgically implanted through the oral mucosa and gingiva to provide support and a means of retention for a dental prosthesis.	C
39	Zinc polycarboxylate dental cement	A non-sterile substance intended for professional use as a dental cement (e.g., luting agent, liner, base) and/or direct dental restorative material whereby the majority of the setting reaction is based on the hardening reaction between zinc oxide (ZnO) and aqueous solutions of polycarboxylic acid (e.g., polyacrylic acid).	B
40	Transmandibular implant	A sterile transosteal (transosseous) device [transmandibular implant (TMI)] intended to be surgically implanted through mandibular bone to provide support and a means of retention for a dental prosthesis, especially in a patient with an extremely atrophied/deformed mandible.	C

41	Pliable-polymer dental regeneration membrane, bio absorbable, ligated	A sterile bio absorbable material intended to be used to aid in the regeneration of tooth support, lost due to periodontal disease or trauma, by acting as a barrier to prevent the down-growth of soft tissue (connective tissue and epithelial cells) into the underlying bone during the healing period.	C
42	Pliable-polymer dental regeneration membrane, bio absorbable, tacked	A sterile bio absorbable material intended to be used to aid in the regeneration of tooth support, lost due to periodontal disease or trauma, by acting as a barrier to prevent the down-growth of soft tissue (connective tissue and epithelial cells) into the underlying bone during the healing period.	C
43	Dental surgical procedure kit, medicated, reusable	A collection of various dental instruments, dressings, pharmaceuticals and the necessary materials used to perform a dental surgical procedure.	C
44	Dental surgical procedure kit, medicated, single-use	A collection of various sterile dental instruments, dressings, pharmaceuticals and the necessary materials used to perform a dental surgical procedure.	C
45	Membrane fixation tack, bio absorbable	A sterile bio absorbable tack intended to be used to fix a pliable-polymer dental regeneration membrane in situ to aid in the regeneration of tooth support that has been lost due to periodontal disease or trauma.	C
46	Periodontal root surface regeneration material	A bio absorbable material intended to be used alone or in combination with bone graft materials for the regeneration of tooth support that has been lost due to periodontal disease or trauma. It is applied during periodontal flap surgery to the scaled and preconditioned root surface and forms an insoluble matrix that creates a suitable root surface for selective periodontal cell migration and cell attachment, which re-establishes the lost tooth support.	C
47	Periodontal tissue reconstructive material	A sterile viscous material intended to be injected into the buccal mucosa to treat deficiencies of the gingiva (e.g., interdental papillae), through augmentation, during the treatment of intermediate stage periodontal disease.	C
48	Bone matrix implant, human-derived	A sterile implantable device made primarily of human demineralized bone matrix (DBM) intended to fill bony voids or gaps caused by trauma or surgery, including use in the maxillofacial and/or mandibular bone.	C
49	Collagen dental regeneration membrane	A sterile, bio absorbable, animal-derived collagen (e.g., porcine) intended to be used to aid in the regeneration of tooth support, lost due to periodontal disease or trauma, and/or to regenerate bone or bone defects around dental implants and at sites intended for implant placement, by acting as a barrier to prevent the down-growth of soft tissue into the underlying bone during the healing period.	C
50	Dental cotton roll	It is intended as an absorbent, hard-packed cylinder (a roll) that is used as a saliva absorber from the oral cavity during dental procedures. It may also be used as a packing between the lip/cheek and the gum to give better examination/operative exposure.	A

51	Dental impression tray, single-use	The device is used mainly to facilitate the manufacturing of custom dental prostheses (e.g., dentures). This is a single-use device.	A
52	Preformed dental crown, permanent	A prefabricated prosthetic device designed to function as a permanent artificial covering to partially or fully replace the damaged crown of a tooth. It is available as a single prosthesis or multiple prostheses of various shapes and sizes, and may include one or more try-in prosthesis replicas and other devices intended to assist the restoration procedure.	B
53	Preformed dental crown, temporary	This device is commonly used during prosthodontic treatment or other restorative work required as a result of traumatic injury.	B
54	Zinc phosphate dental cement	A non-sterile substance intended for professional use as a dental cement and/or direct dental restorative material whereby the majority of the setting reaction is based on the hardening reaction between an oxide powder [the principal constituent of which is zinc oxide (ZnO)] and an aqueous solution of phosphoric acid.	B
55	Dental articulation paper forceps	A hand-held manual dental instrument designed for grasping and holding articulation paper during its application to a patient's oral cavity.	A
56	Dental dressing forceps, reusable	A hand-held manual dental instrument designed for grasping and holding a dental dressing during its application to a patient's oral cavity.	A
57	Dental dressing forceps, single-use	A sterile, hand-held manual dental instrument designed for grasping and holding a dental dressing during its application to a patient's oral cavity.	A
58	Rubber dam clamp forceps	A hand-held dental instrument used for the insertion and removal of rubber dam clamps.	A
59	Tooth extraction forceps	A hand-held manual dental surgical instrument shaped like pincers and designed for the extraction of teeth.	A
60	Dental amalgam mercury dispenser	A device with a valve intended to measure and dispense into a mixing capsule a predetermined amount of dental mercury in droplet form which is to be used to produce amalgam filling material.	A
61	Dental anaesthesia injection kit	A collection of sterile devices designed to inject dental anaesthetics into gingival tissue or the oral mucosa, while preventing or reducing the risk of accidental needle-stick injury, during restorative or surgical dental procedures.	B
62	Dental anaesthesia syringe cartridge	A plastic or glass container prefilled with a single dose of anaesthetic medication intended to be inserted into a dental anaesthesia syringe and injected into oral tissues for a dental procedure.	C
63	Dental anaesthesia syringe, intraligamentary	A hand-held manual dental instrument intended to be used to inject an anaesthetic agent under pressure via the periodontal ligament or into bone through an attached sterile needle. This is a reusable device.	C
64	Dental anaesthesia syringe, reusable	A hand-held manual dental instrument intended to be used for injecting an anaesthetic agent, subcutaneously or intramuscularly, from a prefilled, single-use cartridge through an attached sterile needle; a needle is not included.	B

65	Dental anaesthesia syringe, single-use	A sterile, hand-held, manual dental instrument intended to be used for injecting an anaesthetic agent, subcutaneously or intramuscularly, from a prefilled, single-use cartridge through an attached sterile needle (needle not included).	B
66	Dental anaesthesia syringe/needle	A hand-held manual dental instrument intended to be used for injecting an anaesthetic agent, subcutaneously or intramuscularly, from a prefilled, single-use cartridge through an included sterile needle; the needle may be attached or detached.	B
67	Dental anaesthesia system	An assembly of devices used for the administration of a proportional mixture of oxygen (O2) and nitrous oxide (N2O) or medical air during dental surgical treatment.	C
68	Bite registration rim	A schematic model of the dental arch attached to a temporary or permanent base for recording jaw relationships.	B
69	Bite registration rim wax	A dental material (modelling wax) with or without reinforcing foils (metal, polymer) for registration of jaw relation (making bite rims). This is a single-use device.	A
70	Bite registration rim wax, plate	A dental material (modelling wax) delivered as prefabricated plates of wax with or without reinforcing foils (metal, polymer) for registration of jaw relation (making bite rims).	B
71	Calcium hydroxide dental cement	Use as a dental cement and/or direct dental restorative material whereby the majority of the setting reaction is based on the hardening reaction between calcium hydroxide and salicylic acid.	B
72	Ceramic artificial teeth	Prefabricated teeth made of ceramic (porcelain) for mounting on removable dentures or fixed partial dentures.	B
73	Dental soft-tissue matrix implant, animal-derived	A sterile, bio absorbable, animal-derived collagen (e.g., porcine) intended to be used to aid in the regeneration of oral soft tissue, lost due to periodontal disease or trauma, through promotion of new blood vessels and/or by providing a temporary scaffold for tissue ingrowth; it is indicated for various oral soft tissue augmentation procedures (e.g., alveolar ridge reconstruction, localized gingival augmentation, covering of recession defects and extraction sockets). It is a pliable material which may be fixed to soft tissues with sutures; it is applied to soft tissue during periodontal flap surgery and guided tissue regeneration (GTR) surgical procedures. This is a single-use device.	C
74	Dental Bonding Agents	A dental resin used in the bonding of light cured composites and acid modified composites to tooth structure.	B
75	Dental Etchant	The material is applied for temporary etching of dental hard tissue in order to condition the surface for bonding procedures.	B

76	Dental Prosthesis Priming Agent	A material primarily intended to be applied to a dental prosthesis (i.e., indirect restorative) immediately prior to insertion into a tooth structure to promote bonding to a prosthesis component during a dental procedure in the mouth.	B
77	Restorative Material	A dental luting agent, liner, base, pulp-capping material, pit/fissure sealant, and/or direct dental restorative material for restoration of cavities in teeth.	B
78	Orthodontic Adhesive	Used as a combined etchant and primer in orthodontic treatment used with/without light curing direct bonding orthodontic adhesive.	B
79	Dental Varnishes/ Glazing	A dental device intended to be applied to the surface of a restorative dental filling to attain a smooth, glaze-like finish on the surface.	B
80	Dental Cements	Intended for direct/indirect restoration (temporary/permanent) of tooth.	B
81	Dental Root Surface Conditioner	Assists in the debridement and cleaning of root canals (dental) Aids in the chemical breakdown of pulp soft tissue (dental).	B
82	Dental Cleansing Solution	A liquid used to clean cavities or root canals after preparation, and may also be used for disinfecting the cavity or root canal in endodontic procedures.	B
83	Endodontic Sealer	To fill and seal all pathways between the root canal and external surfaces of the tooth i.e., for permanent obturation of the root canal. Intended for use in procedure involving root filling, repair of root perforations, pulp capping and apexification.	B
84	Oral Cavity Abrasive Polishing Agent	An oral cavity abrasive polishing agent is a device in paste or powder form that contains an abrasive material, such as silica pumice, intended to remove debris from the teeth.	A
85	Root Canal Filling removal Solution	A liquid substance used in endodontic procedures for the softening and removal of root canal fillings. It will typically be introduced into the root canal using instruments. The device typically contains solvents and other elements (e.g., tetrachloroethylene, formamide, eucalyptol, excipients).	B
86	Dental Composite Resin Kit	A collection of non-sterile substances intended for professional use during dental restoration and prosthesis installation/repair which includes composite resin material and additional materials to support restoration (e.g., etching solution, bonding agent, primer, prosthesis bonding agents, unfilled resin sealant/coating agents), and may include dedicated disposable devices associated with application; it does not include non-resin based cement nor dental prosthesis.	B
87	Gingival Bleaching Protector	A non-sterile paste or gel-like substance designed to protect a patients gums from the hydrogen peroxide (H_2O_2) found in teeth whitening agents used during chairside light-curing bleaching of the teeth.	B
88	Dental Caries Removal Solution	A liquid substance used in dentistry to detect and remove caries from an infected tooth.	B

89	Denture Base Resin	A collection of resins and other devices and/or materials intended to be used in the dental laboratory to manufacture a complete or partial denture base (the portion of a denture that rests on the oral mucosa and retains the artificial teeth).	B
90	Polymer Based Prosthodontic Material	Light cured, methacrylate-based resin for creating reservoir space for bleaching trays is useful for laboratory procedures such as model, and die repair. It can be block out defects and under cuts on the stone models quickly and securely for precise abutment preparation.	B
91	Powered Surgical Drill Hand piece for Dental applications	A device that consists of a hand piece to which is connected a variety of attachments in order to achieve a number of cutting/inserting/trimming operations.	B
92	Orthodontic appliance, Band	Device for fixed orthodontic appliances. Device affixed to contour of tooth/teeth and cemented into place to support (pressure can be exerted on the teeth) orthodontic appliances or attachments.	B
93	Orthodontic Elastomeric	A tooth positioner/instrument intended to control settling/position and to minimize or eliminate relapse of the teeth after an orthodontic treatment.	A
94	Orthopaedic dental file	A hand-held dental surgical instrument used to enlarge the root canal, smooth out the root canal wall or shaping canals after they are previously cleaned by scratching/scraping with vertical reciprocating motion or rotary motion or plucking motion.	B
95	Dental endodontic enlarger	A device for enlarging and preparing the root canal, which probes, enlarges, and cleans the root canal by dental file, etc. The motion of the file includes vibrating, rotating, repeating rotation, reciprocating, and a combination of these motions.	B